


Deviation Request Form (DRF)

Directions: The Initiator will complete Sections A through C. Additional continuation pages can be included if necessary.

Initiator	Cori Martin			Date	7/11/2023			
A. Requested deviation applies to (Technical Procedure – include specific section):								
DNA Database Administrative Policy and Procedure								
B. Requested deviation:								
2.1 The organizational chart for the Section reflects chain of command and responsibilities (e.g., technical leader, CODIS state administrator, safety officer, etc.). Areas in which the Forensic Scientist has shown competency is documented on the work authorization record. The date of qualification will be used to define the applicable version of QAS used to access education, experience, and training.								
C. Necessity for the deviation:								
To clarify that the date of qualification will be used for determining the applicable QAS version to be used when assessing education, experience, and training requirements.								
D. Technical review and Authorization (to be completed by the Quality Manager and/or Technical Leader)								
Comments(to include merits and impacts):								
Approved	<input checked="" type="checkbox"/>	Yes	<input type="checkbox"/>	No	Duration	Until next procedure revision.		
Signature				Digitally signed by Cori Martin Date: 2023-07-11 11:13:52	Date	7/11/2023		
E. Quality Assurance Authorization (to be completed by the Quality Manager, Forensic Scientist Manager or designee)								
Acceptable within general QA guidelines and good laboratory practice?					<input checked="" type="checkbox"/>	Yes	<input type="checkbox"/>	No
Significant negative impact to Crime Laboratory Quality System?					<input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No
Restrictions/limitations:								
<input checked="" type="checkbox"/>	Authorized	<input type="checkbox"/>	Rejected	Signature	Zach Kallenbach		Date	7/11/2023
					<small>Digitally signed by Zach Kallenbach DN: cn=Zach Kallenbach, o=NC State Crime Laboratory, OU=DNA Database, E=z.kallenbach@ncdoj.gov, C=US Reason: I am the author of this document Location: Date: 2023-07-11 11:29:44 Fossil PhantomPDF Version: 9.1.0</small>			

DNA Database Administrative Policy and Procedure

1.0 Purpose - To ensure the following:

- 1.1** The DNA Database Section meets the standards set forth in the State Crime Laboratory Quality Manual and the FBI Quality Assurance Standards for DNA Databasing Laboratories, ISO 17025 and supplemental requirements.
- 1.2** The DNA Database Section provides the North Carolina Criminal Justice System services for DNA typing and ensures that these procedures are operating within established performance criteria.
- 1.3** Provide a repository for DNA samples from individuals pursuant to Article 13 of Chapter 15A of the North Carolina General Statutes.
- 1.4** The quality and integrity of the data are maintained and are scientifically sound.
- 1.5** Corrective actions are documented.
- 1.6** The DNA Database Section provides guidelines to employees so they are aware of performance expectations.
- 1.7** Personnel performing tests have the appropriate level of training and education.
- 1.8** DNA Database Forensic Scientists, Supervisors, and Managers are competent in performing testing and interpreting the results to the extent in which they participate. This shall be done through a series of proficiency tests.

2.0 Scope - This procedure applies to all personnel assigned to the State Crime Laboratory DNA Database Section.

- 2.1** The organizational chart for the Section reflects chain of command and responsibilities (e.g., technical leader, CODIS state administrator, safety officer, etc.).

3.0 Procedure

3.1 Responsibilities

3.1.1 DNA Database Forensic Scientist Manager

- 3.1.1.1** Manage Database employees.
- 3.1.1.2** Ensure the Section has procedures where required.
- 3.1.1.3** Ensure that the procedures are followed.
- 3.1.1.4** Work with the Technical Leader to ensure validations and procedural modifications are performed as needed.
- 3.1.1.5** Work with the Technical Leader to approve any variations in procedures.

- 3.1.1.6** Respond to or assign a designee to respond to requests from criminal justice/governmental agencies regarding Database information and release information only as specified in Article 13 of Chapter 15A of the North Carolina General Statutes.
- 3.1.1.7** Authorize removal of Database samples from databank.
- 3.1.1.8** Disseminate or assign a designee to disseminate CODIS hits among DNA Database Forensic Scientists, request subject information assessments, and perform combined technical/administrative reviews of CODIS hits.
- 3.1.1.9** Ensure the initiation of the processing of expungement requests upon receipt of the AOC-CR-640 verification form by creating the expunction request record in SpecMan for compliance within the statutorily required period.
- 3.1.1.10** Ensure the assignment of expungement requests to Criminal Justice Specialists and DNA Database Forensic Scientists, verify the removal of the DNA record from all applicable locations, witness the destruction of samples and collection cards which qualify for expungement, and complete the final verification step within SpecMan confirming completion of the expungement process.

3.1.2 Forensic Scientist Supervisor

- 3.1.2.1** Supervise Database employees.
- 3.1.2.2** Respond to requests from criminal justice/governmental agencies regarding Database information and release information only as specified in Article 13 of Chapter 15A of the North Carolina General Statutes.
- 3.1.2.3** Other duties as assigned by the Forensic Scientist Manager.

3.1.3 DNA Technical Leader

- 3.1.3.1** Duties as described in the Quality Manual.
- 3.1.3.2** Other duties as assigned by the Forensic Scientist Manager.

3.1.4 DNA Database Forensic Scientists

- 3.1.4.1** Respond to requests from criminal justice/governmental agencies as to whether a DNA sample from a particular person is on file.
- 3.1.4.2** Receive and process Database samples.
- 3.1.4.3** Perform analysis of Database samples.
- 3.1.4.4** Interpret data and develop DNA profiles from Database samples.
- 3.1.4.5** Complete CODIS confirmations and perform technical and combined technical/administrative reviews.
- 3.1.4.6** Enter profiles into CODIS.
- 3.1.4.7** Process approved expungement requests; remove the DNA profile of the sample from

the DNA Database, and destroy the sample retained within the Databank within the statutorily required time period.

3.1.4.8 Other duties as assigned by the Forensic Scientist Manager.

3.1.5 DNA Database Technicians

3.1.5.1 Respond to requests from criminal justice/governmental agencies as to whether a DNA sample from a particular person is on file.

3.1.5.2 Receive and process Database samples.

3.1.5.3 Perform analysis of Database samples. Technicians do not interpret data to reach conclusions on typing results or prepare final documents.

3.1.5.4 When using DNA Database procedures, a DNA Database Technician shall follow the instructions for a DNA Database Forensic Scientist for all section procedure components he/she will perform.

3.1.5.5 Other duties as assigned by the Forensic Scientist Manager.

3.1.6 Criminal Justice Specialists (CJS)

3.1.6.1 Respond to requests from criminal justice/governmental agencies as to whether a DNA sample from a particular person is on file.

3.1.6.2 Receive and process Database samples.

3.1.6.3 Generate subject information assessments upon request from Forensic Scientist Manager or designee.

3.1.6.4 Process assigned expunction requests to completion and generate approval/denial expunction letters for mailing within the statutorily required time period.

3.1.6.5 Complete criminal history queries as requested for Crime Laboratory applicants and intern applicants.

3.1.6.6 Other duties as assigned by the Forensic Scientist Manager.

3.1.7 Temporary Employees

3.1.7.1 Respond to requests from criminal justice/governmental agencies as to whether a DNA sample from a particular person is on file.

3.1.7.2 Receive and process Database samples.

3.1.7.3 Other duties as assigned by the Forensic Scientist Manager.

3.1.8 CODIS Administrator/Assistant CODIS Administrator

3.1.8.1 Respond to requests from criminal justice/governmental agencies regarding Database information and release information only as specified in Article 13 of Chapter 15A of the North Carolina General Statutes.

- 3.1.8.2** Obtain CODIS hits and notify Forensic Scientist Manager of CODIS hits.
- 3.1.8.3** Expunge profiles of individuals who do not have a qualifying event.
- 3.1.8.4** Send letter to requesting NDIS/LDIS laboratory upon completion of a CODIS hit.
- 3.1.8.5** Verify the deletion of profiles entered into CODIS which qualify for expunction within the statutorily required time frame.

3.1.9 Laboratory Legal Counsel

- 3.1.9.1** Respond to requests regarding whether a sample is acceptable or whether a sample has a qualifying offense.
- 3.1.9.2** Review the subject information assessment and supporting documentation when there is a CODIS hit to a sample that may not have a qualifying offense.
- 3.1.9.3** Review the assigned expunction requests and provide legal review/recommendation for the approval or denial. This recommendation shall be documented in SpecMan.

3.2 Facilities

3.2.1 Section secure areas:

- Areas that house database samples for long term storage.
- Areas where samples are actively being stored during non-business hours or when DNA Database employees are not currently in the section.

3.3 Access to Data and Information

- 3.3.1** Access to information in the Database and Databank is permitted only as specified in Article 13 of Chapter 15A of the North Carolina General Statutes. All other requests for information shall be denied. Requests for information shall be accepted only from law enforcement or criminal justice agencies, or governmental forensic science laboratories. Requests from private forensic laboratories shall not be honored.
- 3.3.2** The identity of any person/agency making a request for information shall be verified prior to the release of any information. To verify the identity of the person requesting the information, the Database employee shall obtain the individual's name and agency name.
- 3.3.3** Approved personnel may access the following law enforcement databases to obtain information to process samples in the DNA Database Section or in relation to their official job duties.
 - 3.3.3.1** Division of Criminal Information Network (DCIN/Omnixx)
 - 3.3.3.1.1** Administrative Office of the Courts (AOC)
 - 3.3.3.1.2** Computerized Criminal History (CCH)
 - 3.3.3.2** North Carolina Warrant Repository (NCAWARE)
 - 3.3.3.3** North Carolina Department of Public Safety (NC DPS)

3.3.3.4 Criminal Justice Law Enforcement Automated Data Services (CJLEADS)

Note: The Forensic Scientist Manager may authorize the use of an additional law enforcement tool (i.e. database, software, or portal) as it becomes available. The Forensic Scientist Manager may revoke the use of any new or existing law enforcement tools by the section or by individual employees.

3.4 Electronic Records

- 3.4.1** Information regarding the processing of Database samples including accessioning, analysis, review, CODIS hit confirmations, and expunction requests shall be stored electronically in SpecMan. An audit trail for each sample shall be maintained in this system.
- 3.4.2** DNA profiles shall not be stored in SpecMan.
- 3.4.3** Laboratory analysis documentation for proficiency tests and training samples (if applicable) shall be entered and stored in FA.
- 3.4.4** Analysis documentation for in-house runs and CODIS hit confirmations shall be maintained on the server.

3.5 Documentation

- 3.5.1** Corrections to collection cards shall be made with a single strike through of the record and shall be initialed and dated.
- 3.5.2** Any additional information added to the collection card shall be initialed and dated.
- 3.5.3** Any typed notes added to a specimen record in SpecMan shall be initialed and dated. Comments are not required for attachments that are scans of documents from the agency.
- 3.5.4** Any telephone call made to the submitting agency to obtain information about a sample shall be documented in the notes section of the specimen record. At a minimum, the following shall be included: the name of the individual and agency, the date of call, and a summary of the conversation. The note shall be initialed and dated by the individual making the call.
- 3.5.5** All files shall be generated in such a manner that another trained DNA Database Forensic Scientist can follow and understand all the steps taken during the analysis (including decision making steps).
- 3.5.6** Analysis shall be documented in the DNA Database Forensic Scientist's notes as it is conducted or in the event of extenuating circumstances (e.g., court, FA/instrument issues, sick leave), the Forensic Scientist shall complete the worksheets at the earliest opportunity thereafter.
 - 3.5.6.1** If samples are to be reanalyzed at any step, that step of the process officially begins when the instrument is started. At that point, documentation shall be maintained in the DNA Database Forensic Scientist's notes.

3.6 Continuing Education

- 3.6.1** Section Forensic Scientists shall complete a minimum of 8 hours of continuing education each calendar year. This requirement shall be met in one or more of the following ways: by attending

seminars, college courses, professional meetings or by taking on-line courses. DNA online courses shall be submitted to the Technical Leader (TL) for review and approval prior to participation. Forensic Scientists shall stay current on developments within the field by reading current scientific literature and signing the appropriate acknowledgement sheet as documentation. Forensic Scientists shall have access to the internet and local university libraries for reading scientific literature. The TL or designee shall circulate literature when pertinent scientific literature is published.

- 3.6.2** The official continuing education training records shall be stored electronically in the Learning Management System (LMS). A copy may be maintained within the Section.

3.7 Validation

- 3.7.1** This Laboratory shall use only validated methods and procedures for the analysis of convicted offender, arrestee, and employee samples.

3.7.2 Developmental and Internal Validation of the DNA Analysis Procedures

All developmental and internal validation studies shall be performed according to the FBI Quality Assurance Standards for DNA Databasing Laboratories (Standard 8) and the SWGDAM Validation Guidelines for Forensic DNA Analysis Methods.

- 3.7.3** Validation studies, population studies, and research project results shall be maintained in the DNA Database Section by the Forensic Scientist Manager or designee.

3.8 Proficiency Tests

- 3.8.1** All DNA Database Forensic Scientists shall follow the procedure for proficiency testing as outlined in the Laboratory Procedure for Ensuring the Quality of Test Results. In addition, all proficiency vendors shall meet FBI Quality Assurance Standards for DNA Databasing Laboratories. DNA Database Forensic Scientists shall complete an external proficiency test semi-annually in accordance with QAS standards. If a DNA Database Forensic Scientist is on extended leave during the period of time the proficiency test is to be analyzed, he/she shall complete an internal competency test prior to returning to the bench for analysis and subsequently return back into the next cycle of the proficiency testing program.

- 3.8.2** DNA Database proficiency tests shall be documented in FA. Documentation shall be as similar to CODIS hit documentation as possible.

- 3.8.3** DNA Proficiency tests shall be reviewed and recorded on a Proficiency Test Evaluation Form which contains the elements required by the FBI Quality Assurance Standards for DNA Databasing Laboratories (Standard 13).

- 3.8.4** All final reports shall be graded by the Technical Leader as satisfactory or unsatisfactory. A satisfactory grade is attained when there are no analytical errors for the DNA profile typing data.

- 3.8.5** All proficiency test participants shall be given feedback from the Technical Leader which shall be documented. In the event of non-administrative discrepancies that affect the typing results, the CODIS Administrator shall be informed of the results of the proficiency test.

- 3.8.6** The due date for DNA External Proficiency Tests shall be the date used to monitor the semi-

annual tests for DNA Database Forensic Scientists.

3.8.7 Storage of proficiency tests - For storage and retention schedule, see the State Crime Laboratory Procedure for Ensuring the Quality of Test Results.

3.9 **Corrective Action** – The CODIS Administrator shall be notified when a nonconformity impacts DNA records entered into CODIS. For other information regarding Corrective Actions, see the State Crime Laboratory Procedure for Corrective Action and Non-conformities.

3.10 Audits – The Laboratory Procedure for Conducting Audits and Management Reviews shall be referred to for Section wide internal audits. For the purpose of DNA audits (Databasing), the DNA Database Section shall adhere to the FBI Quality Assurance Standards for DNA Databasing laboratories standard 15.

3.11 Subcontracting

3.11.1 The DNA Database section is not currently utilizing a vendor laboratory to provide DNA services for data entry into CODIS. The use of a subcontractor laboratory for convicted offender/arrestee sample testing is permitted. Most often this will take place as part of a coordinated outsourcing program to specific laboratories chosen for this work.

3.11.2 Criteria for Subcontractor Selection

3.11.2.1 The criteria for evaluating prospective subcontractor labs include, but are not be limited to, the following: compliance with the proposal, adherence to quality standards (audit report and responses), personnel, equipment/materials/facilities, security, evidence handling procedures, proficiency testing, documentation, validation, safety, analytical procedures, data interpretation and reporting, etc.

On-site visits: When samples are outsourced to a vendor laboratory for DNA analysis, an on-site visit of the vendor laboratory shall be performed. The site visit shall be performed prior to the initiation of analysis. Additionally, an on-site visit shall be conducted every year the outsourcing contract is active and vendor analysis is occurring. The site visit shall be performed by the Technical Leader or designee from the DNA Database Section and shall certify that the laboratory meets or exceeds the FBI Quality Assurance Standards and compliance with the accreditation requirements of federal law. A memorandum shall be generated by the employee(s) conducting the site visit and that documentation shall be retained by the DNA Database Section. The memorandum shall include the date the on-site visit was performed, a summary of the visit, and documentation of the employee who performed the on-site visit.

Alternatives to an on-site visit: The Technical Leader may elect to accept information/documentation generated from an on-site visit conducted of the vendor laboratory by an NDIS laboratory using the same technology, platform, and typing amplification test kit as long as it was conducted within the past twelve months; or, the Technical Leader may accept an on-site visit conducted by a designated FBI employee within the past twelve months. This acceptance shall be documented by the Technical Leader in a memorandum.

3.11.3 Prior to submission of convicted offender/arrestee samples for testing at a subcontractor laboratory, the following must be performed and documented:

3.11.3.1 The Technical Leader shall issue a memorandum approving the technical specifications of the outsourcing agreement.

3.11.3.2 An on-site visit or an alternative to an on-site visit of the vendor laboratory shall be documented.

3.11.3.3 Section procedures shall be updated to include:

3.11.3.3.1 Random reanalysis of outsourced samples.

3.11.3.3.2 Quality control sampling of outsourced samples.

3.11.3.3.3 Technical review of outsourced sample data.

3.11.3.3.3.1 A review of all DNA types to verify that they are supported by the raw and/or analyzed data.

3.11.3.3.3.2 A review of all associated controls, internal lane standards, and allelic ladders to verify that the expected results were obtained.

3.11.3.3.3.3 Verification of the DNA types, eligibility, and the correct specimen category for entry into CODIS.

3.11.4 The DNA Database Section and the contracting laboratory shall ensure that an appropriate chain of custody is maintained at all times.

3.11.5 Prior to uploading or accepting data to upload or search in CODIS from any vendor laboratory or agency the Technical Leader shall document the approval of the technical specifications of the outsourcing agreement and/or document the approval of acceptance of the ownership of the DNA data.

3.11.6 The DNA Database Section shall maintain the documentation of the:

3.11.6.1 Vendor laboratory's compliance with the FBI Quality Assurance Standards for DNA Databasing Laboratories.

3.11.6.2 On-site visit or the alternative to an on-site visit of the vendor laboratory.

3.12 Uncertainty of Measurement – The DNA Database Section acknowledges that its measurements have a minimal level of uncertainty. Since there are no quantitative results reported from the Section, it produces no measurements that require application of an uncertainty measurement formula.

4.0 Staff Index – The DNA Database Section shall be responsible for the analysis and upload of staff, vendor, or visitor profiles to be included in the "Staff" index in CODIS. Profiles shall be uploaded to CODIS within 15 business days of receipt of sample or as soon as practical thereafter.

5.0 Safety – Refer to the State Crime Laboratory Safety Manual.

6.0 References

Federal Bureau of Investigation “QUALITY ASSURANCE STANDARDS FOR DNA DATABASING LABORATORIES.” *July 1, 2012* ISO 17025

Scientific Working Group on DNA Analysis Methods “Validation Guidelines for DNA Analysis Methods.” *December 2012.*

State Crime Laboratory Document Control and Management Procedure

State Crime Laboratory Procedure for Conducting Audits and Management Reviews

State Crime Laboratory Procedure for Ensuring the Quality of Test Results

State Crime Laboratory Quality Manual

State Crime Laboratory Safety Manual

7.0 Records

- DNA Database Proficiency Test Evaluation Form
- Key inventory
- Duty list
- Reviewer list
- Work authorizations
- Vendor list
- DNA Database Section equipment inventory

8.0 Attachments – N/A

Revision History		
Effective Date	Version Number	Reason
08/09/2021	7	3.2.1-Clarified section secure areas; Added 3.3.3 and subsections; Added 3.5.1-3.5.4; Updated References